

Upon entry of this amendment, claims 31, 34, 37-50 will be pending.

Summary of the Amendment

New claim 37 is provided in place of canceled claim 1. Support for new claim 37 can be found throughout the specification and claims as originally filed. No new matter has been added. New claim 37 is consistent with the election requirement, as it covers the elected species. New claim 37 presents the claimed subject matter in a newly formatted formula which makes the claim more clear and definite. Applicants have replaced the variables X and Y in the amino acid sequence with α and β in order to avoid any potential confusion. Moreover, the formula employs the symbol Φ to represent the sequence which is repeated according to the formula n times where n is 1 to 1000. As the formula clearly indicates, Φ is 25 amino acids or less.

The substitution of claim 1 with new claim 37 clarifies Applicants' intention that the claim does not cover the **entire** viral protein from which the peptides are derived. As amended, the claim cannot read on the entire protein. With respect to the phrase "consisting essentially" and the application of prior art, Applicants respectfully urge that neither claim 1 nor new claim 37 reads on the entire viral protein. Applicants urge that the subject matter of claim 1 as well as that of claim 37 is clearly distinguished from the art reporting the entire viral protein.

New claim 38 is provided in place of canceled claim 36 and refers to specific embodiments of the present invention. Support for new claim 38 is found throughout the

specification and claims as originally filed. No new matter has been added. New claim 38 is consistent with the election requirement, as it covers the elected species.

New claims 39 and 40 refer to specific embodiments of the invention. Support for new claims 39 and 40 is found throughout the specification such as on pages 8, 9 and 31. No new matter has been added. New claims 39 and 40 are consistent with the election requirement, as they cover the elected species.

New claims 41-50 have been added to more clearly define the present invention. New claim 41 provides a formula which clearly defines the metes and bounds of the Applicants' invention. Support for new claim 41 is found throughout the specification, particularly on pages 8 and 9. No new matter has been added. New claims 41-47 are consistent with the election requirement, as they can cover the elected species. New claims 48-50 do not cover the elected species. Upon concluding that claims 31, 34, 37-47 are allowable, Applicants request that claims 48-50 be examined.

Claims 2-30, 32, 33 and 35 have been canceled without prejudice as being directed to non-elected subject matter. Applicants reserve the right to file divisional applications directed to the subject matter of claims 2-30, 32, 33 and 35.

A new abstract has been added to the application. The abstract included herewith is fully supported by the application as filed. No new matter has been added.

Restriction Requirement

Applicants respectfully disagree with the Examiner's interpretation of the patentability of the invention with respect to Group III. Applicants maintain that the grounds for traverse stated in Paper No. 31 were proper. However, because the restriction requirement was made final, and in an attempt to advance prosecution of the elected invention, Applicants will not submit further arguments.

Declaration

Applicants are in the process of obtaining a new Declaration in compliance with 37 CFR 1.67(a) that identifies the present application and corresponding filing date. Applicants will submit the Declaration in due course. In addition, Applicants intend to claim priority under 35 U.S.C. § 120 to the parent application, U.S. Patent Application Serial No. 07/945,280, filed September 15, 1992.

Abstract

It was asserted that the application did not contain an abstract. Applicants note that an abstract was included in the PCT application for which this application is a U.S. National Stage Application. It appears that the abstract was not included in the application when the PCT application entered the national stage. Applicants have amended the application to include a new

abstract of the disclosure. The application is in compliance with the requirements of 37 C.F.R. 1.72(b).

Rejection under 35 U.S.C. § 112, first paragraph

Claim 31 stands rejected under 35 U.S.C. § 112, first paragraph, because those skilled in the art having read the specification allegedly would not be able to practice the claimed inventions. Applicants respectfully request reconsideration of this rejection, as there is no reason of record to believe that one of ordinary skill in the art would not be able to practice the claimed invention.

The Office Action suggests that the art is unpredictable and would require undue experimentation and that an animal model would be required to practice the claimed invention. However, a close inspection of the Office Action not only reveals that these factors do not support the rejection of the present claim, but, rather, indicates that any experimentation associated with practice of the claimed invention would be routine and well within the level of the skill in the art.

The Office Action mischaracterizes the disclosure of the Jackman et al. reference as stating that:

Jackman et al. teach that in order to establish whether an EBV related protein would even be tested to determine that said protein could be used to treat EBV related disease in humans, that it was necessary to obtain appropriate in vivo data in an appropriate in vivo preclinical model such as cottontop tamarins.

Applicants respectfully submit that Jackman et al. do not state that *in vivo* data is necessary. The cottontop tamarin *in vivo* model described in Jackman et al. is merely exemplary, not predictive. There is nothing in Jackman et al. that suggests that in the absence of such an *in vivo* model, one of ordinary skill in the art would think that EBV-related proteins would not be effective. Jackman et al. does not say that an *in vivo* model is necessary to predict effectiveness. Jackman et al. does not say that *in vitro* data is not predictive. Applicants respectfully urge that Jackman et al. reports an *in vivo* model but does nothing to establish that *in vitro* data is not predictive or that the *in vivo* model is required. Contrary to the Examiner's characterization of Jackman et al., an *in vivo* animal model is not required to show the probability of success. It is sufficient to provide data that is consistent with the belief of one skilled in the art that the claimed invention would be effective. Nothing in Jackman et al. would lead one skilled in the art to question the predictive value of the *in vitro* data and require data from an *in vivo* model.

When considering enablement under 35 U.S.C. § 112, paragraph one, the test is whether one of ordinary skill in the art would consider the data sufficient to support the claim. Jackman et al. merely provide an example of a possible model for measuring effectiveness. There is no suggestion that the cottontop tamarin or any other animal model is a superior indication of effectiveness. Furthermore, Applicants respectfully submit that one of ordinary skill in the art would determine that the serological data provided in the present application is sufficient to enable the present claimed invention and that the art-skilled would have ample information in

order to determine the effectiveness of the EBV-related proteins. Thus, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection under 35 U.S.C. § 102(f)

Claims 1, 31, 34 and 36 were rejected under 35 U.S.C. §102(f) because the Applicants allegedly did not invent the claimed subject matter. Applicants respectfully request reconsideration of this rejection as the documents of record, copies of which are provided herewith, indicate the inadvertent omission of Susan Pothen Varghese as an inventor in the PCT application, WO 94/06470.

Applicants submit herewith a copy of the October 23, 1996 Renewed Petition Under 37 CFR 1.48(a) with the accompanying Verified Statement of Facts signed by Smith, Pearson and Parks; Declaration of John R. Wetherell; the Assignment; Declaration and Power of Attorney and Assent of Assignee to Addition to Originally Named Inventors. Also, submitted herewith are Second Renewed Petition and a corrected Assent of Assignee, dated May 30, 1997 along with the Filing Receipt dated March 13, 1998, which reflects Susan Pothen Varghese as an inventor.

The foregoing documents, which have been already made of record, reflect the inadvertent omission of Susan Pothen Varghese as an inventor of the invention claimed in WO 94/06470. The foregoing documents establish that the inventors of claimed invention in the

instant application are the same as those who should have been named in WO 94/06470.

Therefore, the totality of evidence establishes that the rejection under §102(f) in view of the WO 94/06470 publication is obviated. Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection under 35 U.S.C. §102(b)

Claims 1, 31, 34 and 36 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Smith et al. WO 94/06470. Applicants respectfully submit that the corrected Declaration referred to above will permit claiming priority back to WO 94/06470. Claiming priority to WO 94/06470 will eliminate the reference under §102(b) and obviate the rejection.

Claim 1 was rejected as allegedly being anticipated by Pothen et al. (1993). Applicants respectfully submit that the corrected Declaration referred to above will permit claiming priority back to the U.S. parent application, Serial No. 07/945,280, which antedates the Pothen reference. Claiming priority to Serial No. 07/945,280 will eliminate the reference under §102(b) and obviate the rejection.

Claims 1 and 36 were rejected as allegedly being anticipated by Pearson et al. for disclosing the intact protein from which the peptide recited in the claim is derived. Applicants respectfully submit that the rejection is obviated by amendment as discussed above and respectfully request reconsideration and withdrawal of the rejection. Applicants urge that claims

1 and 36 do not claim the entire protein from which the peptides are derived. New claim 37 was added in an attempt to clarify the subject matter claimed. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 31, 34 and 36 were rejected as allegedly being anticipated by Pothen et al. (1991) for disclosing the intact protein from which the peptide recited in the claim is derived. Applicants respectfully submit that rejection is obviated by amendment as discussed above and respectfully request reconsideration and withdrawal of the rejection. Applicants urge that claims 1, 31, 34 and 36 do not claim the entire protein from which the peptides are derived. New claim 37 was added in an attempt to clarify the subject matter claimed. Reconsideration and withdrawal of the rejection is respectfully requested.

Responsiveness

Applicants respectfully urge that this reply is fully responsive to the outstanding official action. Applicants provide this response as a *bona fide* attempt to be fully responsive to the rejections of the claims although the Declaration under 37 CFR 1.67(a) referred to above is not being provided herewith. On July 13, 2000, Applicants' undersigned representative spoke by telephone with Examiner Schwadron on the issue of responsiveness in the absence of submitting an executed declaration with this reply. Examiner Schwadron noted that reference to Applicants' intention to file such a declaration is sufficient to establish a *bona fide* attempt to be fully

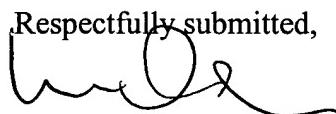
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responsive. Applicants respectfully request that if such a conclusion is reconsidered, that Applicants' undersigned representative be telephoned at 215-568-3100 prior to abandonment of the application so that action can be taken to prevent abandonment. If efforts to contact Applicants' undersigned representative are unsuccessful, Applicants authorize the Patent Office to access the deposit account per the transmittal letter filed herewith to file a request for continuing prosecution under 37 CFR 1.114 to maintain pendency and prevent abandonment of the application.

Conclusion

Applicants respectfully submit that the claims presently before the Examiner patentably define the invention over the prior art and are otherwise in condition for ready allowance.

Respectfully submitted,

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